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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,138	05/09/2001	Geert Maertens	2752-43	4881
23117	7590	01/11/2005	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/851,138

Applicant(s)

MAERTENS ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 63-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63, 65 in condition for allowance if claim 64 and its dependent claims are canceled or amended allowed.
- 6) ☐ Claim(s) 64 and 66-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/28/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment, paper No. 26, filed 10/28/04. Claims 63, 64, 65, 69 have been amended. Claims 1-62 have been canceled. Claims 62-70 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Drawings***

1. The drawings filed on 05/29/2003 has been accepted by the office.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 64, 66, 67, 68, 69 and 70 are still rejected under 35 U.S.C. 112, second paragraph on the same ground as stated in the previous Office Action as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Applicants' traverse the rejection and argue the rejection is not completely understood by the applicants, as it is believed that only one HCV polyprotein, which is the product of translation of a single large open reading frame of the HCV genome, exists. Moreover, applicants submit that a definition of "HCV polyprotein" can be found, for example, on page 9, lines 7-12 of the specification. Further the claims have been amended to indicate the particular part of the HCV polyprotein, which is the subject matter of the claims.

5. Applicant's argument and the amendment filed 10/28/04 have been considered fully, but they are not persuasive. Because HCV is a virus is recognized as positive RNA quasispecies virus that mutates rapidly and automatically in adapting to the environments, thus it has a high

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genome divergence. A single isolated HCV strains even can generate more than a hundred clones in the most genetically heterogeneous region. Therefore, it can translate into more than one kind of HCV polypeptides that have different structural characteristics.

6. Moreover, it is unclear that claim 64 is drafted to be open or closed claim language, what exactly the claimed polynucleotides are intended to encompass. What the claimed polynucleic acid structured is? It is a sequence encoding an entire HCV polyprotein or a portion of the HCV polyprotein?

7. The specification regarding to the definition of HCV polyprotein on lines 7-12 on page 9 has been reviewed. The specification has been defined the HCV polyprotein as the HCV polyprotein of HCV-J isolate (Kato et al. 1990). However, this limitation cannot read into the claim, and the claim as drafted does not limit the claimed HCV polypeptide on the HCV polyprotein disclosed by Kato alone. Therefore, the structural characteristic of claim polynucleic acid sequence is unclear since there is no indication from where the counting of the amino acid residue of claimed HCV polyprotein starts. The rejection is still maintained. This affects the dependent claim 66, 67, 68, 69 and 70.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

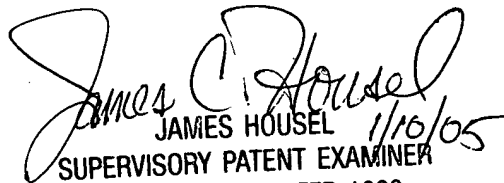
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

1/05/2004

  
JAMES HOUSEL 1/16/05  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600